

## EPARTMENT OF COMMERCE **Patent and Trademark Office**

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| APPLICATION NO. | FILING DATE            | FIRST NAMED INVENTOR |          | ATTORNEY DOCKET NO. |  |
|-----------------|------------------------|----------------------|----------|---------------------|--|
| 09/259,9        | 29 03/01/              | 99 CERAMI            | А        | 10162-004-99        |  |
| Г               |                        | HM12/0612            | EXAMINER |                     |  |
| LAURA A.        | LAURA A. CORUZZI       |                      |          | WEBMAN, E           |  |
| PENNIE &        | EDMONDS                |                      | ART UNIT | PAPER NUMBER        |  |
|                 | NUE OF THE<br>NY 10036 | AMERICAS             | 1 6 1    | · /                 |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

|                                                                                                                                                                                                                                                                                                                                                                                            | Application No.                                                  | Applicant(s)                                                 |                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|--------------------------------------------------------------|-------------------------|
| Office Assign Occurrence                                                                                                                                                                                                                                                                                                                                                                   | 09/259929                                                        | C GRAM.                                                      |                         |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                      | Examiner                                                         | , Group                                                      | Art Unit                |
|                                                                                                                                                                                                                                                                                                                                                                                            | WEBMI                                                            | m                                                            | 617                     |
| —The MAILING DATE of this communication appea                                                                                                                                                                                                                                                                                                                                              | ars on the cover sheet l                                         | beneath the correspo                                         | ndence address          |
| Period for Reply                                                                                                                                                                                                                                                                                                                                                                           |                                                                  |                                                              |                         |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO THIS COMMUNICATION.                                                                                                                                                                                                                                                                                                                       | TO EXPIRE                                                        | MONTH(S) FROM                                                | THE MAILING DATE        |
| <ul> <li>Extensions of time may be available under the provisions of 37 CFR from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a real find period for reply is specified above, such period shall, by defaults.</li> <li>Failure to reply within the set or extended period for reply will, by state.</li> </ul> | reply within the statutory minir<br>t, expire SIX (6) MONTHS fro | mum of thirty (30) days will<br>m the mailing date of this o | be considered timely.   |
| Status                                                                                                                                                                                                                                                                                                                                                                                     | i 1. 4                                                           |                                                              |                         |
| Responsive to communication(s) filed on 12                                                                                                                                                                                                                                                                                                                                                 | 13 / 4 7                                                         |                                                              |                         |
| ☐ This action is <b>FINAL</b> .                                                                                                                                                                                                                                                                                                                                                            |                                                                  |                                                              |                         |
| <ul> <li>Since this application is in condition for allowance excep<br/>accordance with the practice under Ex parte Quayle, 19</li> </ul>                                                                                                                                                                                                                                                  | ot for formal matters, <b>pro</b> s<br>35 C.D. 1 1; 453 O.G. 21  | secution as to the me<br>3.                                  | rits is closed in       |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                      |                                                                  |                                                              |                         |
| Claim(s) 1 - 5 7  Of the above claim(s)                                                                                                                                                                                                                                                                                                                                                    |                                                                  | is/are pending                                               | in the application.     |
| Of the above claim(s)                                                                                                                                                                                                                                                                                                                                                                      | •                                                                | is/are withdray                                              | vn from consideration.  |
| □ Claim(s)                                                                                                                                                                                                                                                                                                                                                                                 |                                                                  |                                                              |                         |
| ☐ Claim(s)                                                                                                                                                                                                                                                                                                                                                                                 |                                                                  |                                                              |                         |
| ☐ Claim(s)                                                                                                                                                                                                                                                                                                                                                                                 | •                                                                | is/are objected                                              | I to.                   |
| ☐ Claim(s) 1 - 5                                                                                                                                                                                                                                                                                                                                                                           | · · · · · · · · · · · · · · · · · · ·                            | are subject to requirement.                                  | restriction or election |
| Application Papers                                                                                                                                                                                                                                                                                                                                                                         |                                                                  |                                                              |                         |
| ☐ See the attached Notice of Draftsperson's Patent Drawin                                                                                                                                                                                                                                                                                                                                  | ng Review, PTO-948.                                              |                                                              |                         |
| ☐ The proposed drawing correction, filed on                                                                                                                                                                                                                                                                                                                                                | is 🗆 approved                                                    | $\square$ disapproved.                                       |                         |
| ☐ The drawing(s) filed on is/are obje                                                                                                                                                                                                                                                                                                                                                      | cted to by the Examiner.                                         |                                                              |                         |
| ☐ The specification is objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                        |                                                                  |                                                              |                         |
| ☐ The oath or declaration is objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                  |                                                                  |                                                              |                         |
| Priority under 35 U.S.C. § 119 (a)-(d)                                                                                                                                                                                                                                                                                                                                                     |                                                                  |                                                              |                         |
| <ul> <li>□ Acknowledgment is made of a claim for foreign priority to</li> <li>□ All □ Some* □ None of the CERTIFIED copies of</li> <li>□ received.</li> <li>□ received in Application No. (Series Code/Serial Numbers)</li> </ul>                                                                                                                                                          | f the priority documents h                                       | nave been                                                    |                         |
| ☐ received in this national stage application from the In                                                                                                                                                                                                                                                                                                                                  | ·                                                                |                                                              |                         |
| *Certified copies not received:                                                                                                                                                                                                                                                                                                                                                            |                                                                  |                                                              |                         |
| Attachment(s)                                                                                                                                                                                                                                                                                                                                                                              |                                                                  |                                                              |                         |
| ☐ Information Disclosure Statement(s), PTO-1449, Paper                                                                                                                                                                                                                                                                                                                                     | Interview Summary, P                                             | ГО-413                                                       |                         |
| ☐ Notice of Reference(s) Cited, PTO-892                                                                                                                                                                                                                                                                                                                                                    | Notice of Informal Pate                                          | ent Application, PTO-152                                     |                         |
| ☐ Notice of Draftsperson's Patent Drawing Review PTO-9                                                                                                                                                                                                                                                                                                                                     | Other                                                            |                                                              |                         |

**Office Action Summary** 

U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

Part of Paper No. 7

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, 32-37, 47-57, drawn to a method of using, classified in class 935, subclass 1+.
- II. Claims 20-31, 38-46, drawn to a product, classified in class 424, subclass 425.

  The inventions are distinct, each from the other because:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be used in a materially different process such as one using cultured cells.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Should applicants elect Group I, the following election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention:

- a.) method for modulating immune response (claims 1-19, 48-50, 55-57).
  - b.) A method for obtaining immune response (claims 32-37, 47).
  - c.) A method for the production of hybridomers (claim 51)

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d.) A method for trasfecting immune cells (claims 52-54)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if generic claim is finally held to be allowable. Currently, immunological methods are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should applicants elect method a.), the following election of species is required:

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Claim 9 generic to a plurality of disclosed patentably distinct species comprising polymers. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should applicants elect method b), the following election of species is required:

Claims 40, 45 are generic to a plurality of disclosed patentably distinct species comprising polymers. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should applicants elect group II, the following election of species is required:

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Claim 25 generic to a plurality of disclosed patentably distinct species comprising polymers. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A restriction by telephone was not attempted in view of the complexity of the requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on M-F from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

C Wehman . M. Moozie:jmr

May 25, 2000

EDWARD J. TEBMAN PRIMARY EXAMINER